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| APPLICATION NO.                  | FILING DATE                           | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|----------------------------------|---------------------------------------|----------------------|-------------------------|------------------|--|
| 10/085,871 02/27/2002            |                                       | Fang-Yu Lee          | 4135P005                | 7742             |  |
| 8791                             | 7590 04/29/2003                       |                      |                         |                  |  |
| BLAKELY SOKOLOFF TAYLOR & ZAFMAN |                                       |                      | EXAMINER                |                  |  |
|                                  | HIRE BOULEVARD, SEVE<br>LES, CA 90025 | ENTH FLOOR           | LILLING, HERBERT J      |                  |  |
|                                  |                                       |                      | ART UNIT                | PAPER NUMBER     |  |
|                                  |                                       | 1651                 |                         |                  |  |
|                                  |                                       |                      | DATE MAILED: 04/29/2003 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application | n No.     | Applicant(s)  |        |  |  |  |
|---|---|-------------|-----------|---|--------|--|--|--|
| Office Action Summary   |   | 10/085,87   |           | LEE ET AL.  |        |  |  |  |
|   |   | Examiner    |           | Art Unit  |        |  |  |  |
|   |   |             | J LILLING | 1651  |        |  |  |  |
|   | The MAILING DATE of this communication app  | ı           |           |   | ddress |  |  |  |
| Period for Reply  |   |             |           |   |        |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |   |             |           |   |        |  |  |  |
| 1)  | Responsive to communication(s) filed on 03.   | June 2002 . |           |   |        |  |  |  |
| 2a)□  | This action is <b>FINAL</b> . 2b) This action is non-final.   |             |           |   |        |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |             |           |   |        |  |  |  |
| Disposit  | ion of Claims   |             |           |   |        |  |  |  |
| 4)🛛   | ☑ Claim(s) <u>1-25</u> is/are pending in the application.   |             |           |   |        |  |  |  |
|   | 4a) Of the above claim(s) is/are withdrawn from consideration.  |             |           |   |        |  |  |  |
| 5)[   | 5) Claim(s) is/are allowed.   |             |           |   |        |  |  |  |
| 6) <u> </u>   |   |             |           |   |        |  |  |  |
| •   | 7) Claim(s) is/are objected to.   |             |           |   |        |  |  |  |
| 8) Claim(s) <u>1-25</u> are subject to restriction and/or election requirement.  Application Papers   |   |             |           |   |        |  |  |  |
| • •   | The specification is objected to by the Examine   | er          |           |   |        |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  |   |             |           |   |        |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |             |           |   |        |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |   |             |           |   |        |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |             |           |   |        |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |   |             |           |   |        |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |             |           |   |        |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |             |           |   |        |  |  |  |
| a)  | ☐ All b)☐ Some * c)☐ None of:   |             |           |   |        |  |  |  |
|   | 1. Certified copies of the priority documents have been received.   |             |           |   |        |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No  |             |           |   |        |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |             |           |   |        |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |   |             |           |   |        |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |   |             |           |   |        |  |  |  |
| Attachment(s)   |   |             |           |   |        |  |  |  |
| 2) Noti   | ce of References Cited (PTO-892)<br>ce of Draftsperson's Patent Drawing Review (PTO-948)<br>mation Disclosure Statement(s) (PTO-1449) Paper No(s) | ·           |           | nary (PTO-413) Paper N<br>nal Patent Application (P |        |  |  |  |

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- 1. Receipt is acknowledged of the prior art information disclosure statement filed June 03, 2002 and the sequence data, which have been approved on January 16, 2003 as being properly entered into the file.
- 2. Claims 1-25 are present in this instant application.
- 3. Restriction to one of the following inventions is required under 35 U.S.C.121:
  - I. Claims 1-2, drawn to Saccharothrix microorganisms having number YS-44442 and YS-45494 and their mutants thereof, classified in class 435, subclass 252.1
  - II. Claims 3-12, drawn to a process for producing pravastatin, classified in class 435, subclass125.
- III. Claims 13-25, drawn to a process for isolating pravastatin, classified in Class 435, subclass 243.
- 4. The inventions are distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the microorganism as

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claimed can be used in a materially different process of using that product, e.g., obtaining glucanases enzymes from the species.

Invention III does not require the specifics of Inventions I or II.

- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is** (703) 308-2034 and **Fax Number** is for applications **Before Final** (703) 872-9306 and **After Final** for applications is 703-872-9307 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL (703) 308-2034 Art Unit <u>1651</u> April 25, 2003

Dr. Herbert J. Lilling Primary Examiner

Haly Silven

Group 1600 Art Unit 1651